In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 16-0731V
Filed: March 13, 2018
UNPUBLISHED

COURTNEY P. BINETTE, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Processing Unit (SPU); Entitlement; Ruling on the Record; Decision Without a Hearing; Causation-In-Fact**;** Influenza ("Flu") Vaccine**;** Shoulder Injury Related to Vaccine Administration (SIRVA)

Leah VaSahnja Durant, Law Offices of Leah V. Durant, PLLC, Washington, DC, for petitioner.
Robert Paul Coleman, III, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT [1]

Dorsey, Chief Special Master:

On June 22, 2016, Courtney P. Binette ("petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa–10, *et seq*.[2] (the "Vaccine Act" or "Program"), alleging that as a result of receiving an influenza ("flu") vaccination on October 25, 2015, she suffered from a shoulder injury related to vaccine administration ("SIRVA"). Petition at 1. The case was assigned to the Special Processing Unit ("SPU") of the Office of Special Masters. For the reasons discussed herein, the undersigned finds that petitioner is entitled to compensation.

[1] Because this unpublished ruling contains a reasoned explanation for the action in this case, the undersigned intends to post it on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Procedural History

Petitioner filed medical records in support of her June 22, 2016 petition. Pet.'s Exs. 1-7 (Vaccination and Medical Records), ECF No. 6; Pet.'s Ex. 8 (Pet.'s Aff.), ECF No. 10; Pet.'s Ex. 9 (Updated Medical Records), ECF No. 15; Pet.'s Exs. 10-11 (Dr. Piscopo Records), ECF No. 31; Pet.'s Ex. 12 (JoAnn Lanoie Aff.), ECF No. 33; Pet.'s Ex. 13 (Letter from Vocational Expert Roberta Hurley), ECF No. 34.

An initial status conference was held on July 26, 2016. Order, ECF No. 9. During that conference, a schedule was set for petitioner to file an affidavit and for respondent to file initial feedback in the case. *Id.*

On September 12, 2016, respondent filed a status report indicating he was amenable to engaging in settlement discussions, ECF No. 11. Periodic status reports were filed updating the undersigned on the progress of settlement. *See* ECF Nos. 13, 16, 18, 20, & 24.

On March 1, 2017, respondent informed the court via email that the parties had reached a tentative settlement agreement and requested that the undersigned issue a 15-week stipulation order. 15-Week Order, ECF No. 25 (withdrawn). A July 31, 2017 deadline was set for the filing of the parties' stipulation of settlement. *Id.*

On June 13, 2017, respondent reported that the authorized representative of the Attorney General had declined to grant settlement approval for the parties' proposed tentative settlement. Resp.'s Status Report, ECF No. 26. As a result, the undersigned convened a status conference on July 13, 2017. Order, ECF No. 27. During that conference, the undersigned issued a preliminary finding that petitioner's claim would qualify as a SIRVA claim. *Id.* A schedule was set for briefing for a ruling on the record and petitioner was directed to file her damages documentation. *Id.* Following the conference, the undersigned also withdrew the March 1, 2017 15-Week Order. *See* Order, ECF No. 27.

Petitioner filed her motion for ruling on the record on September 18, 2017, ECF No. 32. Respondent filed a memorandum in response on October 18, 2017, ECF No. 35. Petitioner did not file a reply. On December 20, 2017, the undersigned issued an order introducing two medical articles discussing SIRVA as court exhibits: B. Atanasoff et al., *Shoulder injury related to vaccine administration (SIRVA)*, 28 Vaccine 8049 (2010), filed as **Court Exhibit I**, and M. Bodor and E Montalvo, Vaccination Related Shoulder Dysfunction, 25 Vaccine 585 (2007), filed as **Court Exhibit II**. *See* Order, ECF No. 36. The parties were directed to file any responses by January 19, 2018. *Id.* No responses were filed and the matter is now ripe for ruling.

II. Applicable Legal Standards

Under Section 13(a)(1)(A) of the Act, a petitioner must demonstrate, by a preponderance of the evidence, that all requirements for a petition set forth in section 11(c)(1) have been satisfied. A petitioner may prevail on her claim if the vaccinee for whom she seeks compensation has "sustained, or endured the significant aggravation of any illness, disability, injury, or condition" set forth in the Vaccine Injury Table (the Table). § 11(c)(1)(C)(i). The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. § 14(a). If petitioner establishes that the vaccinee has suffered a "Table Injury," causation is presumed.

If, however, the vaccinee suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, petitioner must prove that the administered vaccine caused injury to receive Program compensation on behalf of the vaccinee. § 11(c)(1)(C)(ii) and (iii). In such circumstances, petitioner asserts a "non-Table or [an] off-Table" claim and to prevail, petitioner must prove her claim by preponderant evidence. § 13(a)(1)(A). This standard is "one of . . . simple preponderance, or 'more probable than not' causation." *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1279-80 (Fed. Cir. 2005) (referencing *Hellebrand v. Sec'y of Health & Human Servs.*, 999 F.2d 1565, 1572-73 (Fed. Cir. 1993). The Federal Circuit has held that to establish an off-Table injury, petitioners must "prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1351 (Fed. Cir 1999). *Id.* at 1352. The received vaccine, however, need not be the predominant cause of the injury. *Id.* at 1351.

The Circuit Court has indicated that petitioners "must show 'a medical theory causally connecting the vaccination and the injury'" to establish that the vaccine was a substantial factor in bringing about the injury. *Shyface,* 165 F.3d at 1352-53 (quoting *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Circuit Court added that "[t]here must be a 'logical sequence of cause and effect showing that the vaccination was the reason for the injury.'" *Id.* The Federal Circuit subsequently reiterated these requirements in its *Althen* decision. *See* 418 F.3d at 1278. *Althen* requires a petitioner

> to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. All three prongs of Althen must be satisfied. *Id.*

Section 11(c)(1) also contains requirements concerning the type of vaccination received and where it was administered, the duration or significance of the injury, and the lack of any other award or settlement. *See* § 11(c)(1)(A),(B),(D) and (E). With regard to duration, a petitioner must establish she

> (i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization **and** surgical intervention.

§ 11(c)(1)(D) (emphasis added).

III. Analysis - Althen Prongs

a. A Medical Theory Causally Connecting the Vaccination and Injury

To satisfy the first *Althen* prong, the petitioner must show that the vaccination in question can cause the injury alleged. *See Pafford v. Sec'y of Health & Human Servs.*, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *aff'd*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). The petitioner must offer a medical theory which is reputable and reliable. *See, e.g.*, *Pafford*, 451 F.3d at 1355 (reputable); *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010) (reliable). The petitioner must prove this prong by preponderant evidence. *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1350 (Fed. Cir. 2010).

i. SIRVA Injury

Effective for petitions filed beginning on March 21, 2017, SIRVA is an injury listed on the Vaccine Injury Table ("Table"). See Vaccine Injury Table: Qualifications and aids to interpretation. 42 C.F.R. § 100.3(c)(10). Although petitioner's claim was filed before SIRVA was added to the Table, and thus cannot be found to be a SIRVA Table injury, the undersigned's findings are informed by the Qualifications and Aids to Interpretation for SIRVA criteria used to evaluate such claims. The criteria are as follows:

A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following: (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection; (ii) Pain occurs within the specified time-frame; (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial

neuritis, mononeuropathies, or any other neuropathy). *Id.; see also* National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, Notice of Proposed Rulemaking, July 29, 2015 (citing Atanasoff S, Ryan T, Lightfoot R, and Johann-Liang R, 2010, *Shoulder injury related to vaccine administration (SIRVA)*, Vaccine 28(51):8049-8052).

1. The elements of petitioner's SIRVA claim

The undersigned's findings and conclusions are as follows:

a. Petitioner did not have a history of pain, inflammation or dysfunction of the affected shoulder prior to vaccine intramuscular administration.

The undersigned reviewed Ms. Binette's medical history prior to her October 2015 flu vaccination. Petitioner did not have a history of pain, inflammation or dysfunction of her left shoulder prior to vaccination. Thus, petitioner satisfies this criterion.

b. Onset occurred within the specified time frame.

Respondent argues that petitioner has not established that her left shoulder pain began within 48 hours from her October 25, 2015 flu vaccination. Resp.'s Resp. at 7. Respondent's further asserts that petitioner's recollection as to the onset of her shoulder pain is inconsistent and thus, unreliable. *Id.* at 8. The undersigned disagrees.

On October 25, 2015, petitioner received a flu vaccination intramuscularly in her left upper arm. Pet.'s Ex. 1 at 1. Although petitioner often reported to her providers thereafter that she received the flu shot on October 22, 2015 instead of October 25, 2015, she consistently reports that her pain began directly following the vaccination. *See* Pet.'s Ex. 3 at 18 (dated 11/9/2015, "states limited ROM since 10/22/2015 flu shot via her employer, left side, having trouble with all activity and sleeping); Pet.'s Ex. 4 at 48 (dated 11/19/2015, "P[atient] reports history of l[eft] [shoulder] pain since flu shot received 10-22-15."); Pet.'s Ex. 2 at 1-2 (dated 1/5/2016, "Here for left shoulder pain since 10/22/15 when she had the flu vaccine."); Pet.'s Ex. 2 at 3 (dated 1/5/2016, "Symptoms started 10/22/15 when she received her flu shot."); Pet.'s Ex. 6 at 7 (dated 2/26/2016, "She reports within a day or 2 she was having significant pain in her shoulder and difficulty with use of her arm.").

Furthermore, petitioner's coworker, JoAnn Lanoie, recalls petitioner having difficulty performing aspects of her job due to shoulder pain immediately following her October 25, 2015 flu shot. Pet.'s Ex. 12 at 1; *see also* Pet.'s Ex. 8 at 1 (Pet.'s Aff.).

Based upon the totality of the evidence set forth in the medical records and affidavits, the undersigned finds that the onset of petitioner's shoulder pain was within 48 hours of her October 25, 2015 flu vaccination, and therefore, is within the Vaccine Table specified time frame of $\leq$48 hours. § 13(a)(1)(A) (preponderant standard).

c. Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered.

The evidence submitted by petitioner includes medical records detailing the treatment which she sought for pain in her left shoulder since her October 2015 flu vaccination. *See e.g.,* Pet.'s Ex. 2 at 4, 8; Pet.'s Ex. 3 at 18; Pet.'s Ex. 4 at 48; Pet.'s Ex. 6 at 7-8. A summary of these records follows.

Following her October 25, 2015 flu vaccination, petitioner presented to her primary care physician on November 9, 2015. Pet.'s Ex. 3 at 18. The record from that visit provides:

> The incident occurred at work (Pt states at work on 10/22/2015 she received [sic] a flu shot to the left shoulder and a few days after the shot she has had pain, decreased range of motion and midl [sic] swelling without redness. . . The left shoulder is affected. The incident occurred more than 1 week ago. Injury mechanism: flu shot.

Id. at 19. Petitioner was diagnosed with acute bursitis of the left shoulder. *Id.* at 21.

On December 11, 2015 petitioner's primary care physician referred her to an orthopedic surgeon for an evaluation of her left shoulder pain. Pet.'s Ex. 3 at 16. On January 5, 2016, petitioner was seen by a physician's assistant at Elliot Orthopaedic Surgery for treatment of left shoulder pain. The assessment from that visit was "left rotator cuff tendonitis s/p flu shot" and petitioner was given a steroid injection and an x-ray of her left shoulder was ordered. Pet.'s Ex. 2 at 4-5.

From November 19, 2015 to February 11, 2016, petitioner attended ten physical therapy sessions for her left shoulder. Pet.'s Ex. 4, *passim*. Petitioner returned to her primary care physician on February 15, 2016 reporting ongoing pain and reduced range of motion in her left shoulder. Pet.'s Ex. 3 at 3.

Petitioner underwent an MRI of her left shoulder at Elliot Orthopaedic Surgery on February 21, 2016, the results of which were reviewed by Dr. Mark Piscopo at Elliot Hospital on February 26, 2016 Pet.'s Ex. 2 at 8; Pet.'s Ex. 6 at 7-8. At that visit, Dr. Piscopo explained to petitioner the MRI findings were consistent with rotator cuff tendinosis caused, in his opinion, by petitioner's October 2015 flu vaccination. Pet.'s Ex. 6 at 8. Dr. Piscopo advised petitioner that her diagnosis fell "into the category of shoulder injury related to vaccine administration (SIRVA)" and that "beyond the treatment measures that she has received there does not appear to be any other intervention that is indicated at this time." *Id.* He recommended that additional steroid injections and physical therapy may be considered as needed in the future. *Id.*

Petitioner thereafter continued to seek treatment for her left shoulder pain. On March 31, 2016, petitioner sought a second opinion from orthopedic surgeon, Dr.

Douglas Goumas at New Hampshire Orthopaedic Center. Pet.'s Ex. 5 at 15. Petitioner returned to Dr. Goumas for steroid injection for left shoulder pain on April 1, 2016. *Id.* at 13. During an April 22, 2016 follow-up, Dr. Goumas referred petitioner to additional physical therapy and prescribed Meloxicam for her left shoulder pain. *Id.* at 12.

Petitioner received a third steroid injection for continued left shoulder pain from Dr. Piscopo on September 28, 2016. Pet.'s Ex. 9 at 1-3. Petitioner returned to Dr. Piscopo on January 13, 2017 for ongoing left shoulder pain. Pet.'s Ex. 10 at 1. Dr. Piscopo noted petitioner's left shoulder "continues to show some functional restriction," ordered an MRI of petitioner's left shoulder and advised petitioner that surgery may need to be considered. *Id.* at 2. Petitioner returned to Dr. Piscopo on April 27, 2017 reporting ongoing pain and limited range of motion of her left shoulder and was administered a fourth steroid injection. Pet.'s Ex. 11 at 3.

Based on the records of petitioner's ongoing treatment summarized above, the undersigned finds that the pain and decreased range of motion petitioner experienced are limited to her left shoulder in which she received the flu vaccine. Thus, petitioner has satisfied this criteria.

d. No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

There is no evidence in the record that demonstrates any type of condition or abnormality that would explain petitioner's symptoms.

ii. Logical sequence of cause and effect showing the vaccine was the reason for the injury

Guided by the criteria for evaluating a Table SIRVA injury, the undersigned finds that petitioner has shown, by a preponderance of the evidence, a logical sequence of cause and effect showing that her October 25, 2015 flu vaccine was the reason for her shoulder injury. The SIRVA criteria provides a perfectly logical sequence of cause and effect including (1) no history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection; (ii) Pain occurs within the specified time-frame; (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy). The undersigned has found, *infra*, that petitioner has satisfied all these requirements and thus has satisfied *Althen* prong two.

Moreover, based on the undersigned's knowledge and experience reviewing a large number of SIRVA claims, petitioner's clinical course is consistent with SIRVA.

The undersigned further bases this finding on the previously filed articles, Court Exhibit I (B. Atanasoff et al., *Shoulder injury related to vaccine administration (SIRVA)*, 28 Vaccine 8049 (2010)) and Court Exhibit II (M. Bodor and E Montalvo, Vaccination Related Shoulder Dysfunction, 25 Vaccine 585 (2007)).

iii. Proximate temporal relationship between vaccination and injury

"The proximate temporal relationship prong [under *Althen*] requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *De Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). This analysis involves two inquiries: (1) considering the medical basis of the proffered theory, how long after vaccination would onset or worsening of the disease occur; and (2) did onset or worsening of the disease actually occur in the expected timeframe. The first inquiry necessarily intersects with the prong one analysis. *See Langland v. Sec'y of Health & Human Servs.,* 109 Fed. Cl. 421, 443 (2013); *Veryzer v. HHS*, 100 Fed. Cl. 344, 356 (2011).

As discussed above, under the SIRVA criteria, the onset of the symptoms of petitioner's shoulder injury must begin within 48 hours or less of the vaccination. The undersigned has found that the onset of petitioner's shoulder injury began within 48 hours of the vaccination, and thus, petitioner has satisfied Althen prong two.

IV. Conclusion

A cause-in-fact injury is established when petitioner demonstrates by a preponderance of the evidence: (1) She received a vaccine set forth on the Vaccine Injury Table; (2) She received the vaccine in the United States; (3) She sustained or had significantly aggravated an illness, disease, disability, or condition caused by the vaccine; and (4) the condition has persisted for more than six months. § 13(a)(1)(A). To satisfy the burden of proving causation in fact, petitioner must establish each of three factors announced by the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.* by preponderant evidence: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a proximate temporal relationship between vaccination and injury. 418 F.3d 1274, 1278 (Fed. Cir. 2005). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991).

In light of all of the above, and in view of the submitted evidence, including the medical records and the parties' respective motions, the undersigned finds petitioner entitled to Vaccine Act compensation.

IT IS SO ORDERED.

s/ Nora Beth Dorsey
Nora Beth Dorsey

Chief Special Master